

REMARKS

Claims 1-12 and 26-32 have been examined. In the instant Office Action, the Examiner has raised the following rejections:

- 1) The Drawings are objected to as allegedly ambiguous;
- 2) Claims 1-12 and 26-32 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement;
- 3) Claims 1-12 and 26-32 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement; and
- 4) Claims 1-12 and 26-32 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite.

Applicants have amended Claims 1, 9, 26, 27 and 29, canceled Claims 2-6 and 13-25, and introduced new Claims 33 and 34, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments. Applicants reserve the right to prosecute the original, similar, or broader claims in one or more future application(s).

1) The Drawings Are Unambiguous

The Examiner has objected to the drawings because Figure 2 allegedly appears to suggest that the adenylyl cyclase 7 (AC7) coding sequence, as opposed to the AC7 gene, is 73 kb in length (Office Action, page 2). Although Applicants disagree that Figure 2 is ambiguous, Applicants hereby provide a replacement drawing sheet including Figure 2, in which the 73 kb label and brackets below the schematic of the AC7 gene has been removed. Applicants believe that the amended drawings should be acceptable to the Examiner.

2) The Claims Comply With The Written Description Requirement

The Examiner has rejected Claims 1-12 and 26-32 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that the claims encompass methods of:

identifying individuals predisposed to “major depressive disorder” by detecting “any” polymorphism in “any” adenylyl cyclase 7 (AC7) allele in “any” male or female subject of “any” race. Claim 2 is drawn to a “repeat polymorphism”, while claim 3 limits the polymorphism to [AACA]₇. Claims 4, 5 and 6 limit the subject to Caucasians, females, and subjects that are alcohol dependent, respectively. The claims set forth the structural requirement “any” polymorphism of AC7 are indicative of predisposition to major depressive disorders, although lacking guidance on a functional relationship of how any AC7 polymorphism is associate with major depressive disorder (Office Action, page 3).

Applicants respectfully disagree with this rejection. Nonetheless, Applicants have amended Claims 1, 9, 26, 27 and 29, and canceled Claims 2-6 and 13-25, and introduced new Claims 33 and 34, in order to further the prosecution of the present application and Applicants’ business interests, yet without acquiescing to the Examiner’s arguments, while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). In particular, Applicants have amended Claims 1 and 26 to recite detecting the presence of “an [AACA]₇ repeat polymorphism within the 3’ untranslated region” of an adenylyl cyclase type 7 allele of a nucleic acid sample from a “Caucasian female human subject.” Support for this amendment can be found for instance in original Claims 2-5, now canceled. In addition, Applicants have added new Claims 33 and 34, which recite “wherein said 3’ untranslated region of said adenylyl cyclase type 7 allele comprises a nucleic acid fragment corresponding to nucleotides 5684 to 6062 of SEQ ID NO:1.” Support for the new claims can be found for instance in Example 5, which provides an exemplary method for detecting an [AACA]₇ repeat polymorphism using a primer pair (SEQ ID NOS: 3 and 4) that amplifies a fragment extending from nucleotides 5684 to 6062 of the AC7 mRNA of GENBANK Accession No. NM_001114 set forth as SEQ ID NO:1 (Specification, page 44, lines 10-18). Applicants submit that the teaching of Example 5, in combination with the sequence listing clearly describes the location of the [AACA]₇ repeat polymorphism of interest in AC7 nucleic acids.

The Examiner has also criticized the Specification for allegedly not teaching “how the [AACA]₇ polymorphism alters the structure, function or expression of AC7” (Office Action, page 5). Applicants respectfully submit that the pending claims do NOT require the recited repeat polymorphism to have a direct impact on AC7 structure, function and/or expression. The pending claims simply recite an association between the presence of an [AACA]₇ repeat polymorphism in AC7 nucleic acids with predisposition to major depressive disorder (as

documented in Table 6 of the Specification). This is true even if the [AACA]₇ repeat polymorphism is functionally silent but in linkage disequilibrium with a sequence variation affecting AC7 activity in Caucasian female human subjects.

Applicants submit that the amended claims meet the written description requirement, and accordingly request that this rejection be withdrawn.

3) The Claims Are Enabled

The Examiner has rejected Claims 1-12 and 26-32 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement. The Examiner states that the:

specification, while being enabling for identifying Caucasian females and Caucasian alcohol dependent females predisposed to “major depressive disorders” by detecting the presence of the [AACA]₇ polymorphism in the 3’ UTR, does not reasonably provide enablement for identifying any human, or any female predisposed to “major depressive disorders” by detecting the presence of “any” polymorphism in adenylyl cyclase 7 (AC7)” (Office Action, pages 6 and 7).

Although Applicants respectfully disagree with this rejection, Applicants have amended Claims 1, 9, 26, 27 and 29, canceled Claims 2-6 and 13-25, and introduced new Claims 33 and 34, as described above in Section 2. Applicants contend that the claim amendments render this rejection moot, since the amendments correspond to the embodiments the Examiner has indicated are enabled. Accordingly, Applicants respectfully request that this rejection be withdrawn.

4) The Claims Are Definite

The Examiner has rejected Claims 1-12 and 26-32 under 35 U.S.C. 112, second paragraph, as allegedly indefinite. Specifically, the Examiner has found fault with the use of the phrases “adenylyl cyclase type 7 allele” and “repeat polymorphism” in original Claims 1, 3, 26, 29, and 2 respectively. Although Applicants respectfully disagree with this rejection, as described above in Section 2, Applicants have amended Claims 1, 9, 26, 27 and 29, canceled Claims 2-6 and 13-25, and introduced new Claims 33 and 34. Applicants contend that the claim amendments render this rejection moot, since the amended claims are directed to methods comprising detecting the presence of an [AACA]₇ polymorphism in the 3’ UTR of an AC7 allele

(e.g., any AC7 allele comprising an [AACA]₇ polymorphism in the 3' UTR). As the amended claims are definite, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants believe the arguments and evidence provided herein traverse the Examiner's rejections and, therefore requests that a timely Notice of Allowance be issued in this case. However, should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

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